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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,751	02/09/2004	Jerry R. Grychowski	6298-449	6148
757	7590	08/09/2005		
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610				
			EXAMINER PATEL, NIHIR B	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,751

Applicant(s)

GRYCHOWSKI ET AL.

Examiner

Nihir Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02.09.2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 24-27 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11.01.04; 2.28.05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14 and 24-27, drawn to ventilator circuit apparatus, classified in class 128, subclass 200.14.
- II. Claims 15-23, drawn to an adapter, classified in class 285, subclass 334.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions group I and group II are related as combination and subcombination.

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the inhalation/exhalation tube can be connected to the ventilator without the adapter. The subcombination has separate utility such as being used in plumbing pipes to connect a larger diameter pipe to a smaller diameter pipe.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with **Andrew D. Stover** on **August 2nd, 2005** a provisional election was made **with** traverse to prosecute the invention of **group I, claims 1 through 14 and 24-27**. Affirmation of this election must be made by applicant in replying to

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this Office action. Claims **15-23** are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1 through 3, 9 and 10** are rejected under 35 U.S.C. 102(b) as being anticipated by Brooker et al. (US 6,269,810).

Referring to claim 1, Brooker discloses a pulmonary dosing system and method that comprises a chamber **20** (see **figure 2 and column 4 lines 40-45**) housing defining an interior space and comprising an input end and an output end (see **figure 2**); a one-way inhalation valve **16** (see **figure 2 and column 4 lines 35-40**) positioned upstream of the interior space, the one-way inhalation valve operative to permit a flow of gases into the interior space of the chamber housing; an inhalation conduit **4** (see **figure 2 and column 4 lines 10-15**) communicating with

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the output end of the chamber (see **figure 2**), the inhalation conduit adapted to transmit medication to the patient; an exhaust conduit 5 (see **figure 2** and **column 4 lines 5-10**) communicating with the inhalation conduit; and a one-way exhaust valve 6 (see **figure 2** and **column 3 lines 55-60**) located in the exhaust conduit, the one-way exhaust valve adapted to prevent a back-flow of gas from the exhaust conduit into the inhalation conduit (see **figure 2**).

Referring to claim 2, Brooker discloses an apparatus wherein the inhalation conduit is a first inhalation conduit that further comprises a second inhalation conduit communicating with the input end of the chamber housing, wherein the one-way inhalation valve is located in the second inhalation conduit (see **figure 2**).

Referring to claim 3, Booker discloses an apparatus that further comprises a pressurized metered dose inhaler in flow communication with the chamber housing downstream of the one-way inhalation valve (see **figure 2**).

Referring to claim 9, Booker discloses an apparatus wherein the inhalation conduit comprises a mask 2 (see **figure 3** and **column 3 lines 45-50**).

Referring to claim 10, Booker discloses an apparatus that comprises an adapter 3 (see **figure 2** and **column 3 lines 50-60**) connected to the output end of the chamber housing and comprising a first portion defining at least a portion of the inhalation conduit (see **figure 2**) and a second portion defining at least a portion of the exhaust conduit (see **figure 2**), wherein the one-way exhaust valve is positioned in the second portion of the adapter (see **figure 2**), and further comprising an exhaust lines connected to the second portion and defining at least a portion of the conduit (see **figure 2**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al. (US 6,269,810) in view of Mantz (US 6,527,011).

Referring to claim 5, Brooker discloses the applicant's invention as claimed with the exception of providing inhalation valve that comprises a valve member, a valve seat and a blocking member. Mantz discloses a flexible retainer ring for duckbill valve that does provide a valve that comprises a valve member, a valve seat and a blocking member (see figures 5A and 5B). Therefore it would have been obvious to modify Brooker's invention by providing inhalation valve that comprises a valve member, a valve seat and a blocking member as taught by Mantz in order to provide better control of delivery.

Referring to claim 6, Brooker discloses the applicant's invention as claimed with the exception of providing a valve member that is a center post valve member connected to the valve seat. Mantz discloses a flexible retainer ring for duckbill valve that does provide a valve member that is a center post valve member connected to the valve seat. Therefore it would have been obvious to modify Brooker's invention by providing a valve member that is a center post valve member connected to the valve seat as taught by Mantz in order to provide better control of delivery.

Referring to claim 7, Brooker discloses the applicant's invention as claimed with the exception of providing a blocking member that has at least one opening formed therein to permit the flow of gases therethrough. Mantz discloses a flexible retainer ring for duckbill valve that does provide a blocking member that has at least one opening formed therein to permit the flow of gases therethrough. Therefore it would have been obvious to modify Brooker's invention by providing a blocking member that has at least one opening formed therein to permit the flow of gases therethrough as taught by Mantz in order to provide better control of delivery.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al. (US 6,269,810) in view of Bird (US 6,581,600).

Referring to claim 8, Brooker discloses the applicant's invention as claimed with the exception of providing an inhalation conduit that comprises an endotracheal tube. Bird discloses an interface apparatus and combination and method that does provide an inhalation conduit that comprises an endotracheal tube. Therefore it would have been obvious to modify Brooker's invention by providing an inhalation conduit that comprises an endotracheal tube as taught by Bird in order provide better way of delivering the medication.

Claims 4, 24, 25, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al (US 6,269,810) in view of Banner et al. (US 6,390,091).

Referring to claims 4, 24, 25, 26 and 27, Brooker discloses the applicant's invention as claimed with the exception of providing oxygen as the gas source. Banner discloses a method and apparatus for controlling a medical ventilator that does provide oxygen as the gas source. Therefore it would have been obvious to modify Brooker's invention by providing oxygen or any other type of gas as taught by Banner, in order provide the required treatment.

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Allowable Subject Matter

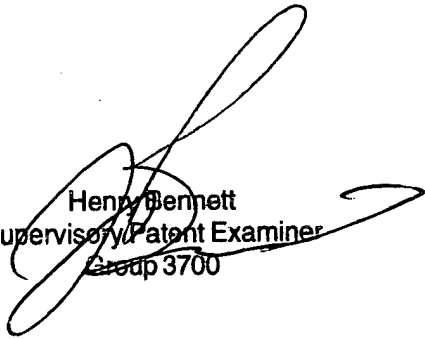
Claims 11 through 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (571) 272 4791.

NP
August 5th, 2005


Henry Bennett
Supervisory Patent Examiner
Group 3700